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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,406	08/15/2003	Richard L. Quick	R0367-03700	1491

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EXAMINER	
SMITH, FANGEMONIQUE A	
ART UNIT	**PAPER NUMBER**
3736	

MAIL DATE	DELIVERY MODE
12/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/642,406	QUICK ET AL.	
	Examiner	Art Unit	
	Fangemonique Smith	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-10,15,16,19,21,71,74,76-85,89-95 and 97-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1, 7-10, 15, 16, 19, 21, 71, 74, 76-85, 89-95 and 97-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Request for Continued Examination filed on September 22, 2008. Examiner acknowledges the amendment of claims 1, 21, 71, 85, 89, 97, 99 and 100; and the cancellation of claim 96. Claims 1, 7-10, 15, 16, 19, 21, 71, 74, 76-85, 89-95 and 97-100 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 7-10, 15, 16, 19, 71, 74, 76, 83-85, 87, 89 and 97-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (U.S. Patent Number 6,758,824) in view of Viola (U.S. Patent Number 6,712,773).

In regard to claim 1, 7-10, 15, 16, 19, 71, 74, 83-85, 87, 89 and 97-100, Miller et al. disclose a tissue biopsy device (10) for accessing and collecting a tissue specimen from a target site within a patient. The biopsy device comprises an elongated probe member (15), which has a proximal end configured to be secured to a drive and an inner lumen (27) extending along a longitudinal axis. Miller et al. describe the probe further having a penetrating distal tip (16) and an aperture (25) proximal to the penetrating distal tip configured to receive tissue from the target site. The Miller et al. device further includes an elongated tissue cutting member (17), which is disposed within the elongated probe member (15), which has at least one tissue cutting edge (35, 36). The

at least one cutting edge creates an angle with respect to the longitudinal axis less than 90 degrees (Fig. 5) and engages a tissue cutting edge (35) of the tissue cutting member.

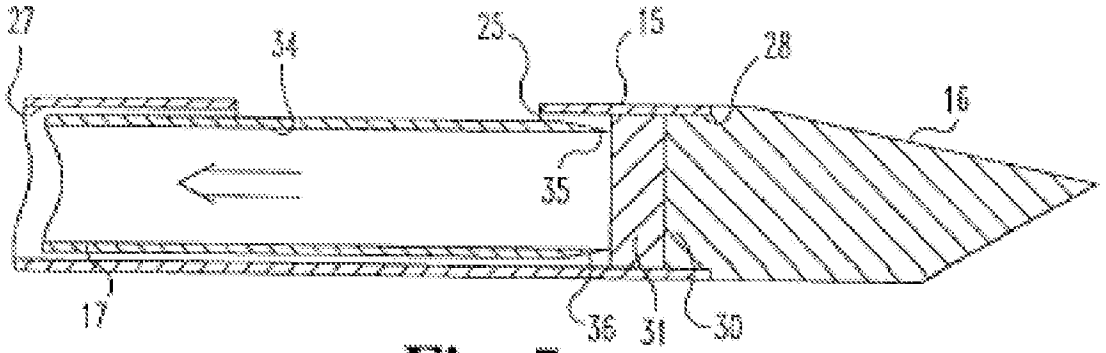

Fig. 5

The tissue cutting member (17) has an inner lumen (34), which is configured to be operably connected to at least one drive unit (22). The inner lumen (34) of the tissue cutting member (17) is further configured to access a vacuum source to transport a tissue specimen through the inner lumen (34) to a tissue collector (55) in fluid communication with the inner lumen. The aperture (25) of the probe (15) has at least one longitudinally oriented tissue cutting edge, which engages a tissue cutting edge (35) of the beveled tip of the tissue cutting member (17). The tissue cutting edge (35) of the tissue cutting member (17) has a tissue cutting angle over a substantial part of its length with respect to the tissue cutting edge of the aperture of about 30 to about 75 degrees (col. 19, lines 15-47). Miller et al. disclose a tissue biopsy device for accessing and collecting a tissue specimen from a target site within a patient. Miller et al. disclose the inner lumen of the tissue

cutting member (17) is configured to access a vacuum source (150) to transport a cut tissue specimen to a tissue collection trap (55) in fluid communication with the inner lumen of the tissue cutting member. The aperture (25) of the probe (15) has at least one longitudinally distally oriented tissue cutting edge, which engages a tissue cutting edge (35) of the beveled needle-like tip of the tissue cutting member (17). The tissue cutting edge (35) of the tissue cutting member (17) has a tissue cutting angle over a substantial part of its length with respect to the tissue cutting edge of the aperture of about 30 to about 75 degrees (col. 19, lines 15-47). Miller et al. disclose the probe comprising an outer member (75), which has a proximal tubular portion (15) configured to be releasably secured to a drive housing (70) and an inner lumen (17) extending therein. A tissue penetrating distal tip (16) is disclosed by Miller et al. The device has an open section (25) proximal to the penetrating distal tip (16) and a supporting strut (30) extending from the penetrating distal tip to the proximal tubular portion (15). Miller et al. disclose an elongated tissue cutting member (17), which is formed at least in part of a tubular member, slidably disposed within the inner lumen of the tissue accessing cannula (43). The tissue cutting member has a tissue cutting edge (35), which has an inner lumen (34) configured to receive a tissue specimen cut by the tissue cutting member. The tissue cutting member (17) is further connected to a drive unit (20) to move the tissue cutting member (17) within the inner lumen of the tissue accessing cannula. The cutting edge (35) of the device is parallel to a longitudinal axis of the tissue cutting member (17) and the tissue cutting member moves longitudinally in a reciprocating motion about the longitudinal axis (col. 8, lines 1-45). The reciprocating motor is capable of moving the tissue cutting member in a reciprocal longitudinal movement of between about 0.01 inch and about 0.2 inch. The tissue accessing cannula (43) has a distal end (28) seated against a

proximal surface of the tissue penetrating distal tip (16) of the outer member. The tissue accessing cannula is operably secured to a drive unit (20) in the drive housing (70) to rotate the tissue receiving cannula (50). In addition, Miller et al. disclose an elongated tissue cutting member (17), which is formed at least in part of a tubular member, slidably disposed within the inner lumen of the tissue accessing cannula (43). The tissue cutting member has a tissue cutting edge (35), which has an inner lumen (34) configured to receive a tissue specimen cut by the tissue cutting member (17). The tissue cutting member (17) is rotatably disposed within the inner lumen of the tissue accessing cannula (34) with a longitudinal axis and a longitudinal tissue cutting edge oriented at an angle with respect to the longitudinal axis. Miller et al. further disclose the tissue cutting member having a non-cutting surface, which defines a tissue receiving aperture along with the tissue cutting edge parallel to the tissue cutting member. The cutting edge of the tissue cutting member further includes a leading distal cutting edge portion and an opposing trailing proximal cutting edge portion. Although Miller et al. disclose a tissue cutting edge having an angle less than 90 degrees with respect to the longitudinal axis, the Miller et al. do not specifically disclose having a longitudinal slot which opens to the tissue receiving opening as described in the amended claims. Viola discloses a biopsy system for retrieving biopsy tissue samples from different regions of a body. The device disclosed by Viola includes a trocar (22) and knife assembly (58). The knife assembly (58) includes a tissue access window (64) and is configured to slidably receive the trocar member (col. 2, lines 45-67; col. 3, lines 1-2). The knife assembly (58) has a longitudinal axis and both a proximal and distal end. The proximal end of the knife assembly has an inner lumen extending therein and is configured to be secured to a drive means (col. 4, lines 40-67; col. 6, lines 10-41). The distal end includes a

penetrating distal tip (60) and the tissue access window (64) of the knife assembly is configured to receive tissue from a target area within a patient (Figs. 32 and 33).

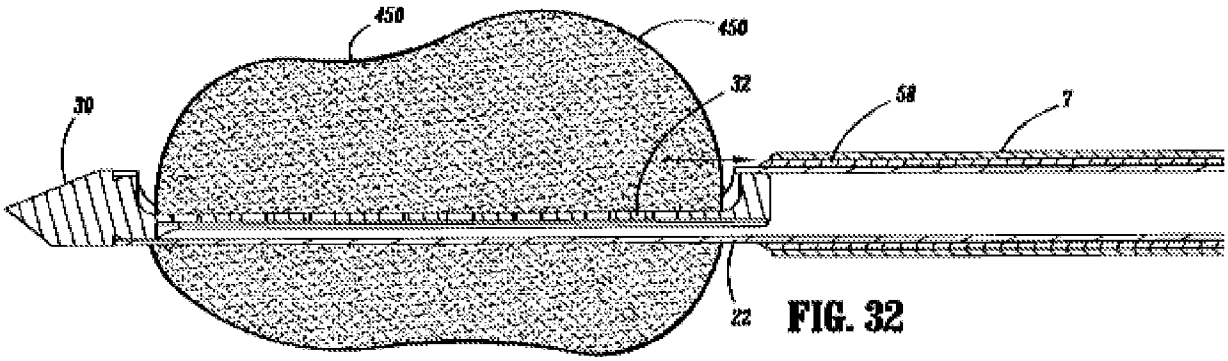

FIG. 32

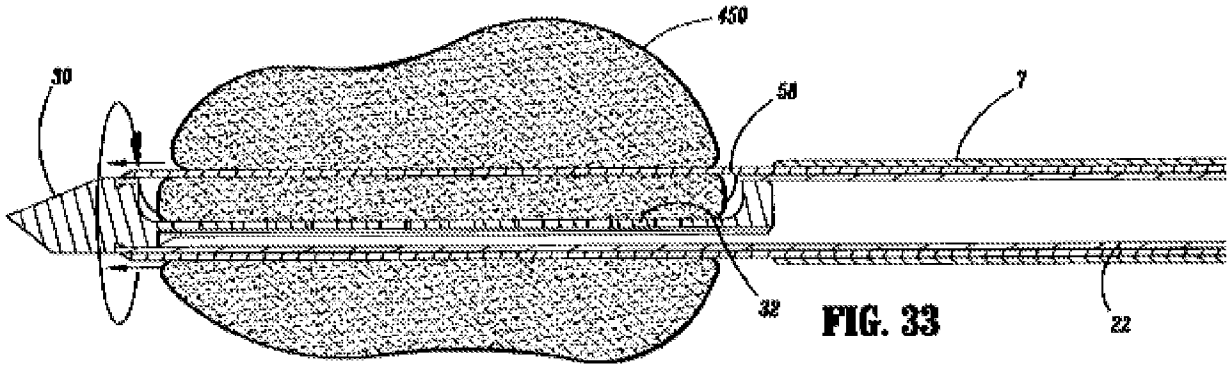

FIG. 33

The elongated trocar has a beveled distal tip with at least one outer tissue cutting edge and a tissue receiving opening with an inner lumen therein (Figs. 32, 33). Viola discloses the inner lumen of the trocar being an open pathway in fluid communication with the tissue receiving opening. Viola further discloses a longitudinally oriented slot (32) within the wall of the distal tubular portion of the trocar. Viola discloses having drivers which move the tissue cutting member of the device about the longitudinal axis. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue biopsy device for accessing and collecting a tissue specimen from a target site, similar to that disclosed by Miller et al., to include a tissue cutting member with a longitudinally oriented slot that opens

to the tissue receiving opening in the beveled distal tip, similar to that disclosed by Viola, to provide a receiving area designed with consideration of the nature of the tissue being biopsied.

4. Claims 1, 7-10, 15, 16, 19, 71, 74, 76, 83-85, 87, 89 and 97-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (U.S. Patent Number 6,758,824) in view of Niederer (U.S. Patent Number 3,902,498).

In regard to claim 1, 7-10, 15, 16, 19, 71, 74, 83-85, 87, 89 and 97-100, Miller et al. disclose a tissue biopsy device (10) for accessing and collecting a tissue specimen from a target site within a patient. The biopsy device comprises an elongated probe member (15), which has a proximal end configured to be secured to a drive and an inner lumen (27) extending along a longitudinal axis. Miller et al. describe the probe further having a penetrating distal tip (16) and an aperture (25) proximal to the penetrating distal tip configured to receive tissue from the target site. The Miller et al. device further includes an elongated tissue cutting member (17), which is disposed within the elongated probe member (15), which has at least one tissue cutting edge (35, 36). The at least one cutting edge creates an angle with respect to the longitudinal axis less than 90 degrees (Fig. 5) and engages a tissue cutting edge (35) of the tissue cutting member.

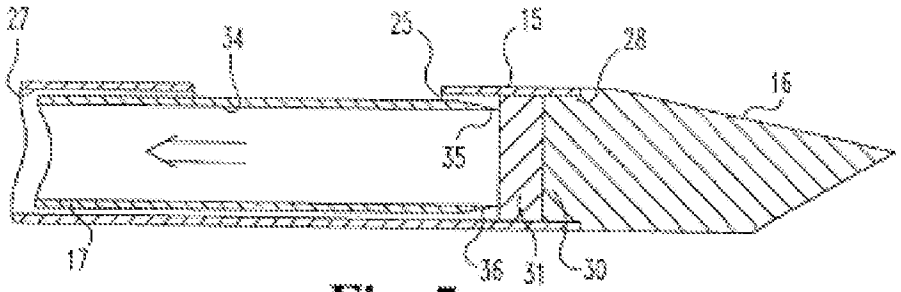

Fig. 5

The tissue cutting member (17) has an inner lumen (34), which is configured to be operably connected to at least one drive unit (22). The inner lumen (34) of the tissue cutting member (17) is further configured to access a vacuum source to transport a tissue specimen through the inner lumen (34) to a tissue collector (55) in fluid communication with the inner lumen. The aperture (25) of the probe (15) has at least one longitudinally oriented tissue cutting edge, which engages a tissue cutting edge (35) of the beveled tip of the tissue cutting member (17). The tissue cutting edge (35) of the tissue cutting member (17) has a tissue cutting angle over a substantial part of its length with respect to the tissue cutting edge of the aperture of about 30 to about 75 degrees (col. 19, lines 15-47). Miller et al. disclose a tissue biopsy device for accessing and collecting a tissue specimen from a target site within a patient. Miller et al. disclose the inner lumen of the tissue cutting member (17) is configured to access a vacuum source (150) to transport a cut tissue specimen to a tissue collection trap (55) in fluid communication with the inner lumen of the tissue cutting member. The aperture (25) of the probe (15) has at least one longitudinally distally oriented tissue cutting edge, which engages a tissue cutting edge (35) of the beveled needle-like tip of the tissue cutting member (17). The tissue cutting edge (35) of the tissue cutting member (17) has a tissue cutting angle over a substantial part of its length with respect to the tissue cutting edge of the aperture of about 30 to about 75 degrees (col. 19, lines 15-47). Miller et al. disclose the probe comprising an outer member (75), which has a proximal tubular portion (15) configured to be releasably secured to a drive housing (70) and an inner lumen (17) extending therein. A tissue penetrating distal tip (16) is disclosed by Miller et al. The device has an open section (25) proximal to the penetrating distal tip (16) and a supporting strut (30) extending from

the penetrating distal tip to the proximal tubular portion (15). Miller et al. disclose an elongated tissue cutting member (17), which is formed at least in part of a tubular member, slidably disposed within the inner lumen of the tissue accessing cannula (43). The tissue cutting member has a tissue cutting edge (35), which has an inner lumen (34) configured to receive a tissue specimen cut by the tissue cutting member. The tissue cutting member (17) is further connected to a drive unit (20) to move the tissue cutting member (17) within the inner lumen of the tissue accessing cannula. The cutting edge (35) of the device is parallel to a longitudinal axis of the tissue cutting member (17) and the tissue cutting member moves longitudinally in a reciprocating motion about the longitudinal axis (col. 8, lines 1-45). The reciprocating motor is capable of moving the tissue cutting member in a reciprocal longitudinal movement of between about 0.01 inch and about 0.2 inch. The tissue accessing cannula (43) has a distal end (28) seated against a proximal surface of the tissue penetrating distal tip (16) of the outer member. The tissue accessing cannula is operably secured to a drive unit (20) in the drive housing (70) to rotate the tissue receiving cannula (50). In addition, Miller et al. disclose an elongated tissue cutting member (17), which is formed at least in part of a tubular member, slidably disposed within the inner lumen of the tissue accessing cannula (43). The tissue cutting member has a tissue cutting edge (35), which has an inner lumen (34) configured to receive a tissue specimen cut by the tissue cutting member (17). The tissue cutting member (17) is rotatably disposed within the inner lumen of the tissue accessing cannula (34) with a longitudinal axis and a longitudinal tissue cutting edge oriented at an angle with respect to the longitudinal axis. Miller et al. further disclose the tissue cutting member having a non-cutting surface, which defines a tissue receiving aperture along with the tissue cutting edge parallel to the tissue cutting member. The cutting edge

of the tissue cutting member further includes a leading distal cutting edge portion and an opposing trailing proximal cutting edge portion. Although Miller et al. disclose a tissue cutting edge having an angle less than 90 degrees with respect to the longitudinal axis, the Miller et al. do not specifically disclose having a longitudinal slot which opens to the tissue receiving opening as described in the amended claims. Niederer discloses a surgical instrument with a first cutting member (4) having a passage therein and a second cutting member (8) slidably received within the passage (Abstract). The device disclosed by Niederer further includes a longitudinal passage (6) in the first cutting member and another tissue accessible recess (10) in the second cutting member (col. 5, lines 35-53). Niederer discloses actuation of the cutting members by means of a motor or other suitable means (col. 5, lines 53-63). Upon accessing a target area with the Niederer device, tissue of the target area enters the longitudinal passage and recess of the device and is severed and stored (Fig. 5).

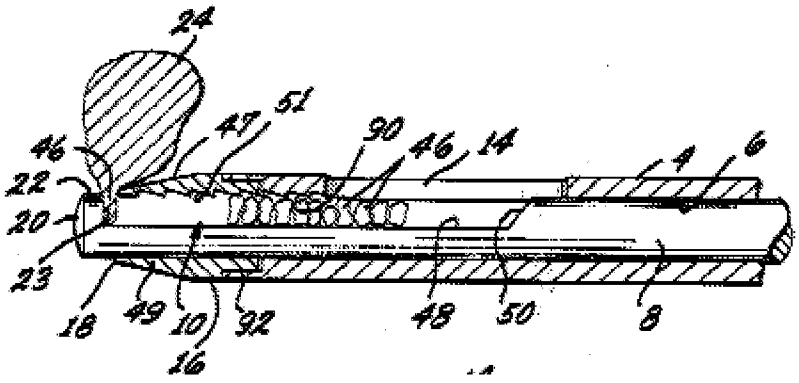

FIG. 5

It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue biopsy device for accessing and collecting a tissue specimen from a target site, similar to that disclosed by Miller et al., to include a tissue cutting member with a longitudinally oriented slot that opens to the tissue receiving opening in the

beveled distal tip, similar to that disclosed by Niederer, to provide a receiving area designed for efficient severing and removal of the tissue being biopsied.

5. Claims 77-82 and 90-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (U.S Patent Number 6,758,824) in view of Viola (U.S. Patent Number 6,712,773) and in further view of Majlessi (U.S Patent Number 5,871,454).

In regard to claims 77-82 and 90-95, the combined references of Miller et al. and Viola disclose the features of the Applicant's invention as described above. The combined references do not disclose a second and third slot opening into the longitudinally oriented slot in a wall of the tubular member. Majlessi discloses a percutaneous excisional biopsy device having a plurality of tissue cutting members radially spaced about the longitudinal axis and strategically positioned at a target site to obtain multiple tissue samples. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue biopsy device for accessing and collecting a tissue specimen from a target site, similar to that disclosed by the combined references of Miller et al. and Viola, to include multiple slotted wall sections of the tubular member, similar to that disclosed by Majlessi, to provide a mechanism which allows collection of multiple samples, while maintaining the functionality of the device.

6. Claims 77-82 and 90-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (U.S Patent Number 6,758,824) in view of Niederer (U.S. Patent Number 3,902,498) and in further view of Majlessi (U.S Patent Number 5,871,454).

In regard to claims 77-82 and 90-95, the combined references of Miller et al. and Niederer disclose the features of the Applicant's invention as described above. The combined references do not disclose a second and third slot opening into the longitudinally oriented slot in a wall of

the tubular member. Majlessi discloses a percutaneous excisional biopsy device having a plurality of tissue cutting members radially spaced about the longitudinal axis and strategically positioned at a target site to obtain multiple tissue samples. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to modify a tissue biopsy device for accessing and collecting a tissue specimen from a target site, similar to that disclosed by the combined references of Miller et al. and Niederer, to include multiple slotted wall sections of the tubular member, similar to that disclosed by Majlessi, to provide a mechanism which allows collection of multiple samples, while maintaining the functionality of the device.

Response to Arguments

7. Applicant argues the prior art reference do not include features of Applicant's invention as amended, Examiner submits Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is (571)272-8160. The examiner can normally be reached on Mon - Fri 8am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

FS

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736